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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
|---|---|---|---|---|
| 10/572,543 | 11/28/2006 | Darcey Clark | X-17671 | 7392 |

25885 7590 02/26/2008

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| EXAMINER | |
|---|---|
| STONE, CHRISTOPHER R | |
| ART UNIT | PAPER NUMBER |
| 1614 | |

| NOTIFICATION DATE | DELIVERY MODE |
|---|---|
| 02/26/2008 | ELECTRONIC |

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

patents@lilly.com

| Office Action Summary | Application No. | Applicant(s) | |
|---|---|---|---|
| | 10/572,543 | CLARK ET AL. | |
| | Examiner | Art Unit | |
| | CHRISTOPHER R. STONE | 1614 | |

*-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --*

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

1)☒ Responsive to communication(s) filed on *10 January 2008*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

4)☒ Claim(s) *69-73* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *69-73* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

**Application Papers**

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date *11/20/2006*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

## DETAILED ACTION

### *Election/Restrictions*

Applicant's election with traverse of gemcitabine, compound 281 (p. 145, WO 2002070494) and non-small cell lung cancer in the reply filed on January 10, 2008 is acknowledged. The traversal is on the ground(s) that the species of compounds and cancers are not the special technical feature of the invention. This is not found persuasive because it is an allegation without factual support.

The requirement is still deemed proper and is therefore made FINAL.

### *Claim Rejections - 35 USC § 103*

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Claims 69-73 are rejected under 35 U.S.C. 103(a) as being unpatentable over Keegan et al (WO 02/07094, provided by Applicant) in view of Gandhi et al (provided by Applicant).

Claims 69-73 are drawn to a method of treating a cell proliferative disorder comprising administering a Chk1 activator, followed by a selective Chk1 inhibitor. Gemcitabine, compound 281 (p. 145, WO 2002070494) and non small cell lung cancer are the elected species of Chk1 activator, Chk1 selective inhibitor and cell proliferative disorder currently under examination.

Keegan et al teaches the administration of gemcitabine and compound 281 for the treatment of human non small cell lung cancer (p. 35, line 21; p. 49, line 33; p. 145, compound 281). Compound 281 is further taught to enhance the therapeutic benefit of chemotherapy with compounds such as gemcitabine (p. 45, lines 19-24; p. 49, line 33; p. 145, compound 281). Keegan et al does not teach the administration of gemcitabine for from about 30 minutes to about 96 hours or the administration of gemcitabine for from about 30 minutes to 48 hours. Gandhi et al teaches the administration of gemcitabine for twelve hours without untoward toxicity (abstract). Gandhi further teaches that this prolonged infusion derives the maximum cytotoxic advantage (p. 671, right column, paragraph 2). Therefore it would have been obvious to one of ordinary skill in the art at the time of the instantly claimed invention to administer gemcitabine for 12 hours, in order to obtain the maximum cytotoxic effect. Keegan et al does not teach the administration of compound 281 for from up to about 1 hour to up to about 72 hours following the administration of gemcitabine; however Keegan

does teach that gemcitabine and compound 281 can be administered in multiple doses at different intervals (p. 50, lines 20 and 21). Therefore, it would have been obvious for one of ordinary skill in the art at the time of the instantly claimed invention to optimize the sequence of administration and infusion duration to determine the regimen with maximum efficacy, thus resulting in the practice of the instantly claimed invention with a reasonable expectation of success. Such routine experimentation is common in the pharmaceutical art. Additionally, Keegan does not explicitly teach that the administration of gemcitabine synchronizes cell cycle arrest among the tumor cells; however this is a property of the composition and is necessary present. It is noted that In re Best (195 USPQ 430) and In re Fitzgerald (205 USPQ 594) discuss the support of rejections wherein the prior art discloses subject matter which there is reason to believe inherently includes functions that are newly cited or is identical to a product instantly claimed. In such a situation the burden is shifted to the applicants to "prove that subject matter shown to be in the prior art does not possess characteristic relied on" (205 USPQ 594, second column, first full paragraph).

***Conclusion***

Any inquiry concerning this communication or earlier communications from the examiner should be directed to CHRISTOPHER R. STONE whose telephone number is (571)270-3494. The examiner can normally be reached on Monday-Thursday, 7:30am-4:00pm EST.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Ardin H. Marschel can be reached on (571) 272-0718. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

05February2008
CRS

/Ardin Marschel/
Supervisory Patent Examiner, Art Unit 1614